

510 (k) SUMMARY**I. GENERAL INFORMATION:****Establishment:**

- Address: Siemens Medical Systems, Inc.
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Iselin, NJ. 08830
- Registration Number: 2240869
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Date of Summary Preparation:**Device Name:**

- Trade Name: Siremobil Compact
- Common Name: Mobile X-ray System
- Classification Name: Mobile X-ray System
- Classification: Class II

Performance Standards:

21 CFR, Subchapter J

All system components to which the above standard applies are certified to conform with 21 CFR subchapter J

II. SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING THE SUBSTANTIAL EQUIVALENCE DETERMINATION.**Device Description:**

The Siremobil Compact is a mobile x-ray C-ram which consists of a high frequency generator, X-ray tube assembly, image intensifier, TV camera, film cassette attachment, Laser light localizers, electronics cabinet and a monitor trolley which consists of the digital memory device, image monitor(s), and user interface. The Siremobil Compact is designed to meet the space and clinical requirements of the clinical environments identified below.

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The Siremobil Compact is designed for easy maneuverability, durability and high efficiency and performance. The system operation is designed to provide the user with an ergonomic clinically optimized interface. The Siremobil Compact can operate in three modes, Fluoroscopy with Last Image Hold, Pulsed Fluoroscopy with Last Image Hold and Digital Radiography. The user can process the images utilizing such techniques as recursive filtration, summation or spatial noise suppression, spatial frequency filtration, motion detector, edge enhancement, and contrast enhancement.

Intended Use:

The Siremobil Compact is a mobile x-ray system intended for use in Operating room, Traumatology, Endoscopy, Intensive Care Station, Pediatrics, Ambulatory patient care and in Veterinary Medicine. The Siremobil Compact can operate in four different modes, Digital Radiography, Fluoroscopy, Pulsed Fluoroscopy and cassette exposures which are necessary in performing wide variety of clinical procedures, such as intraoperative bile duct display, fluoroscopic display of a intra-medullary nail implants in various positions, low dose fluoroscopy in pediatrics, fluoroscopic techniques utilized in pain therapy and positioning of catheters and probes.

Technological Characteristics:

The Siremobil Compact is designed for an optimal range of movement. The rotational, orbital, and angulation movement ranges for the C-arm are as follows: $\pm 12.5^\circ$, 125° (-35 to +90) orbital movement and $\pm 190^\circ$ angulation. The horizontal and vertical movement of the C-arm is optimized for use in clinical applications. The horizontal travel is 20 cm (7.9") and the vertical travel is 45 cm (17.7"). The large C-arm depth, 66 cm (29"), provides the user with excellent patient access during examinations.

General Safety and Effectiveness Concerns:

Instructions for use are included within the device labeling and the information provided will enable the trained healthcare professional to operate the device in a safe and efficacious manner. Furthermore the operators are health care professionals familiar with and responsible for the X-ray examinations to be performed. To minimize electrical, mechanical and radiation hazards, Siemens adheres to recognized and established industry practice, and all equipment is subject to final performance testing.

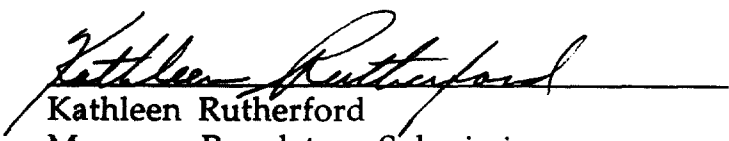
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Substantial Equivalence:

The Siremobil Compact, Mobile X-ray System, has similar technological characteristics and intended uses as the predicate devices described in the Equivalency Information section of this premarket notification. Also, the Laser Targeting Devices (one unit attached to the image intensifier and one unit to attached to the x-ray tube) configured with the Siremobil Compact are the same as the device currently configured with the commercially available Siremobil 2000.

Siemens Medical Systems, Inc. believes that the Siremobil Compact, the subject of this premarket notification, is substantially equivalent to the following medical devices currently in commercial distribution.

Model	Company	FDA K-Number
Siremobil 2000	Siemens Medical Systems, Inc.	K913525
Stenoscop 6000/9000	General Electric, Inc.	K910902
BV 29	Philips, Inc.	K910115
Series 9600	OEC, Inc.	K926056


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8/7/96
Date